Enterprise Buildings Integrator™

Honeywell

RUNNING YOUR BUSINESS FASTER

Honeywell EBI and 21CFR Part 11

Honeywell Enterprise Buildings Integrator ™

Thanks to its Pharma Option, EBI has become the most technically advanced building management solution for the Pharmaceutical industry. EBI is designed for fully FDA and electronic signature conformity. The EBI Pharma Option allows running your business faster.

EBI and the Pharma option

Mainly, Honeywell offers its EBI software suite for use in traditional facility management applications. This includes environmental control systems, energy management systems, life safety systems, control and security system, and power and electrical systems. Even though, EBI software suite is based on an industrial grade software platform ideal for use in mission critical industrial applications. This platform provides EBI with a unique set of "industrial" features that are ideal in critical or validated environments compared to traditional building management solutions.

Or in other words, best suited for HVAC environmental monitoring and control solutions in pharmaceutical industry.

Full support for regulatory expectations

EBI will allow you to supply exact records. Data files are protected and unable to be altered. Because EBI stores the event file relational database tables, which are not encrypted, these data are password protected and are only accessible to the authorized administrators.

But even changes performed by those operators would be recognized at any time by embedded tampering detection mechanism. An advantage of EBI in validated environments is that both the history files and the event file can be archived, which provides the ability to store and then recreate the process operation years later.

Tracking Changes

EBI's robust "Audit Trails" shows what has happened in the system, whether it is process generated or operator actions.

EBI provides a very good solution with its event summary as all operator actions in the system are recorded as an event, which provides a time & date stamp, the operator name, and the event that occurred.

And most important, changes to electronic records do not obscure previous entries.

For example, if a temperature set point was changed, then there is a record in the event file detailing when the change occurred, to what point it occurred, who made the change, the reason for the change, what the original value was, and what the new value is.

Whose clock?

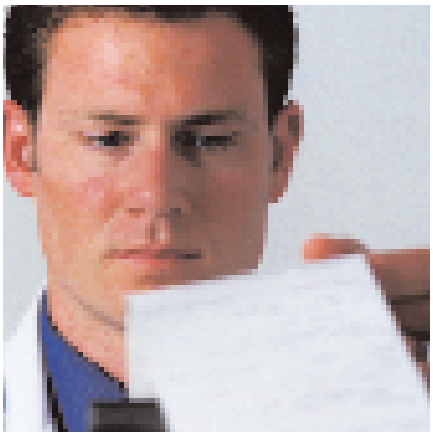
A key aspect of compliance is making sure that the audit trails are in the correct chronological order. The EBI servers can be synchronized with a "Master Clock" on IT group's network so that all EBI events are in the same time reference as other systems on site.

Who did it?– Electronic Signatures

The regulatory focus is around where someone traditionally "signs off" on a paper document that the details on the document are considered true and correct. There is no direct parallel in an environmental control or monitoring system, as operators do not traditionally "approve" data that comes from controllers. As such, the requirements are being interpreted as applying to the users of an EBI system, traditionally called operators which authenticate through an integrated account based on a combination of a Windows user account and an EBI operator definition.

Sign-on to EBI requires the Operator ID and a password, thus meeting the regulations for non-biometric signatures.

Pharma Option

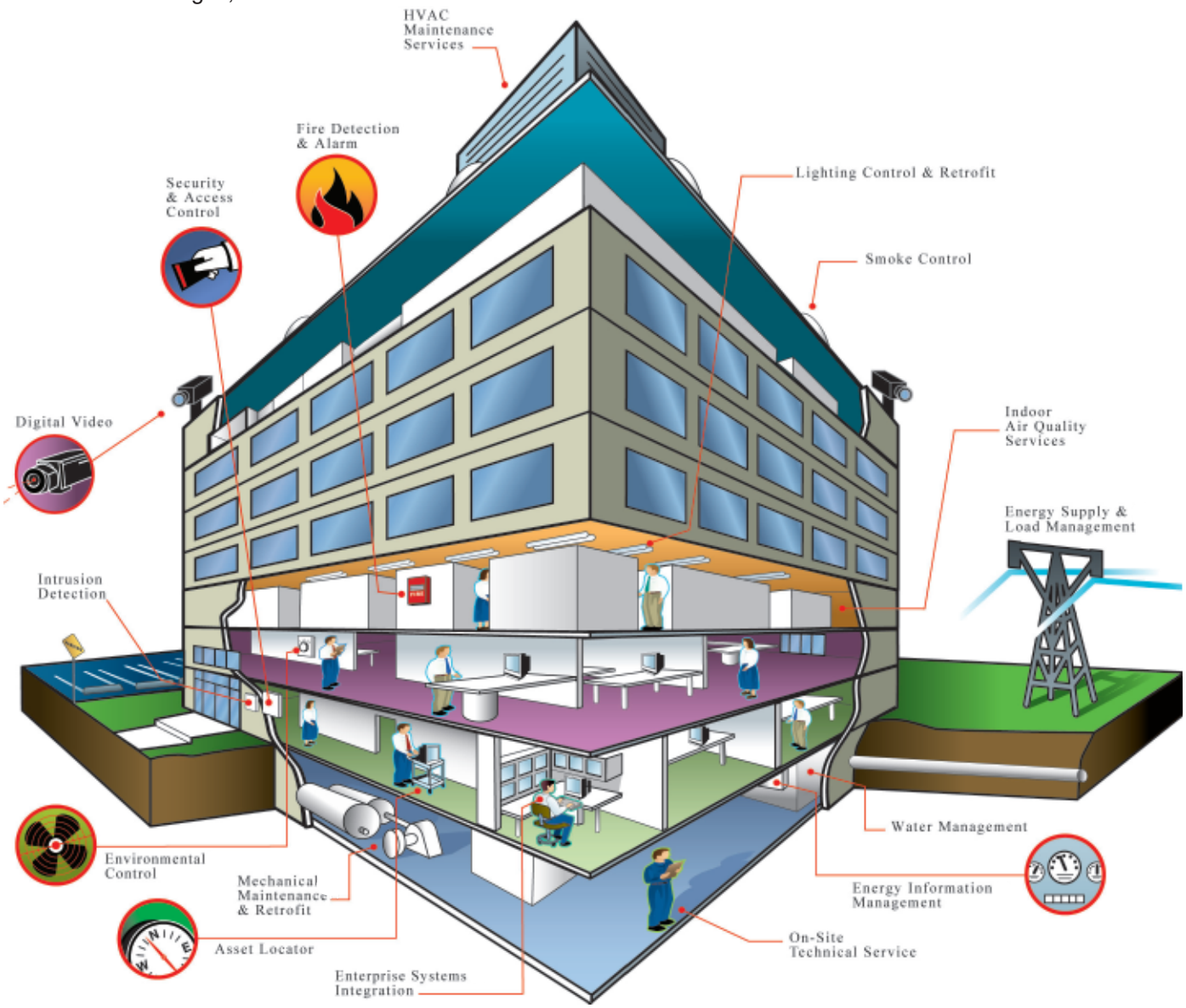


There are also requirements to expire passwords periodically and for automatic logouts based on an idle time period. EBI meets both these requirements. As closed system, EBI authorized operators can make the changes, thus recording the change with the operator ID, full name, and the reason of change on the event file. This fully complied with regulations requiring the name of the signer and the purpose of his session (i.e., review, approval, responsibility, or authorship) is part of the electronic record.

Part 11 Training Program

Although training is generally covered under operational procedures, EBI provides assistance in making sure only trained personnel are using the system.

Operators on the system have a profile that contains information on their security level, control level, area assignments, and starting display.



Areas can be used as a way of segregating operators to only seeing and controlling parts of the process on which they have been trained. When that training occurs, they can then have that area added to their profile online.

Within an area, an operator might be able to monitor and control certain items, but not allowed to control critical equipment without the proper training, or, for instance to control equipment assessed as very critical requiring even double signatures when changes needs to be performed.

Build a system with part 11 in mind

FDA's requirements under 21 CFR Part 11 are based on common sense needs to authenticate and review cGLP and cGMP data. Complying with them is in most cases just good practice.
Even you don't want to have a Part 11 compliant BMS solution yet it is better to build the system with Part 11 in mind than to deal with Part 11 remediation later.

Whether an environmental control system in a research lab or manufacturing area, configured correctly, EBI is an excellent tool in helping Pharmaceutical customers meet their Validation objectives and 21CFR Part 11 compliance.

And, Honeywell Validation Services will bring you to compliancy to most actual regulatory expectations by proven, GAMP conforming delivery and service processes as well as cGMP trained personnel.

Find out more:
For more information please ask for a copy of the EBI's White Paper on "EBI & 21CFR Part 11 for Environmental Systems".

Email: pharma@honeywell.com or call +44 (0) 1344 65 6147 to take advantage

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